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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/073,464	02/11/2002	James Tiedje	MSU-06787	4392

7590 11/05/2004

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EXAMINER
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JOHANNSEN, DIANA B

ART UNIT	PAPER NUMBER
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1634

DATE MAILED: 11/05/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/073,464

**Applicant(s)**

TIEDJE ET AL.

**Examiner**

Diana B. Johannsen

**Art Unit**

1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 01 March 2004 and 09 June 2004.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-15 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-15 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)                        | 4) <input type="checkbox"/> Interview Summary (PTO-413)                     |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____  |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date _____   | 6) <input type="checkbox"/> Other: _____                                    |

Art Unit: 1634

### **FINAL ACTION**

1. This action is responsive to the Amendment and Response filed March 1, 2004 and the complying complete set of claims filed June 9, 2004. Claims 1 and 9 have been amended, and claims 1-15 are now pending and under consideration. Applicants' amendments and arguments have been thoroughly reviewed, but are not persuasive for the reasons that follow. Any rejections not reiterated in this action have been withdrawn. **This action is FINAL.**

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

### ***Election/Restriction***

3. Applicant's election without traverse of Group I (claims 1-15) in the Amendment and Response of July 2, 2003 is again acknowledged. It is again noted that non-elected claims 16-21 have been canceled.

### ***Claim Rejections - 35 USC § 112***

#### **THE FOLLOWING ARE NEW GROUNDS OF REJECTION NECESSITATED BY APPLICANTS' AMENDMENTS:**

4. Claims 7 and 15 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the limitation "said signal." However, claims 1 and 9 (from which claims 7 and 15, respectively, depend) have been amended so as to refer to multiple signals: a "target signal" and a "reference signal." Thus, it is not clear whether claims 7 and 15 are further limiting of the previously recited

Art Unit: 1634

“target signal,” the previously recited “reference signal,” or both. Clarification is required.

***Claim Rejections - 35 USC § 102***

5. Claims 1-15 are rejected under 35 U.S.C. 102(e) as being anticipated by Straus (US 2002/0086289 A1 [published 7/2002; filed 6/1999]), as evidenced by DeRisi et al (Science 278:680-686 [10/1997]), for the reasons stated in the Office action of November 19, 2004.

Straus discloses a method for identifying bacteria in which labeled target DNA from a test sample including bacteria is hybridized to a “detection ensemble” of detection sequences from 5 or more distinct genomes arrayed on a solid support (see entire reference, particular pages 3-4 and the definition of “minimum genomic derivation” at pages 7-8). Straus teaches that in embodiments of his invention, the detection sequences arrayed on a solid support are amplified genomic DNAs (see, e.g., page 17, right column). Straus further discloses both the combination of positive and negative control probes with test sample molecules prior to hybridization (see, e.g., page 19), and preparation of a database of fingerprints with which test sample patterns may be compared (see, e.g., page 28). Regarding the step of “calculating hybridization signal intensity ratio at each array element,” it is noted that Straus states that “Microarrays are scanned with a laser fluorescent scanner, and signals are processed and recorded as is described in published reports,” referring to the DeRisi et al reference (page 25). The DeRisi et al reference discloses that processing and recording of signals comprises calculation of a hybridization signal intensity ratio (see

Art Unit: 1634

entire reference, particularly footnote 49). Accordingly, it is an inherent property of the method disclosed by Straus that it includes such a step, and therefore Straus anticipates the instant claims.

Regarding claims 5 and 9-15, it is further noted that the solid supports disclosed by Straus include microchips (see, e.g., page 10). Regarding claims 2-4 and 10-12, it is noted that the samples disclosed by Straus include samples from a test subject, samples comprising pathogens, and environmental samples (see pages 4, 10, and 12). Regarding claim 6, the processing disclosed by DeRisi et al comprises statistical analysis (see footnote 49 of DeRisi et al).

The response traverses the rejection on the grounds that Applicants' claim amendments overcome the rejection. Specifically, the response notes that claims 1 and 9 have been amended "to recite 'co-hybridizing said target and reference DNA to said arrayed elements' in step b," and argues that Straus does not teach or suggest such a step. The response states that "As shown in Figure 5, Straus teaches hybridization of probe-halves to target DNA attached to a solid support, to select a subset of the probe molecules for subsequent amplification, labeling and hybridization to a detection array," and urges that "Thus, the two separate hybridization steps of Straus are clearly distinct from the single co-hybridization steps recited in amended Claims 1 and 9."

These arguments have been thoroughly considered but are not persuasive for the following reasons. It is again noted that Straus (at, e.g., page 19) clearly teaches the simultaneous hybridization of test and positive control molecules. While it is acknowledged that the method of Straus employs multiple hybridization steps, the

Art Unit: 1634

instant claims recite the open transitional language "comprising," and therefore clearly encompass methods including any type of additional steps, including additional hybridization steps. Further, Applicants' specification does not include, e.g., a limiting type of definition for the term "co-hybridizing" or "co-hybridization" that would exclude the hybridization practiced by Straus. Accordingly, Applicants' arguments are not persuasive.

Straus teaches all the limitations recited in present claims 1-15, and therefore this rejection is maintained.

### **Conclusion**

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Art Unit: 1634

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is 571/272-0744. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 571/272-0745. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

A handwritten signature in black ink, appearing to read "Diana B. Johannsen", followed by a long horizontal flourish.

Diana B. Johannsen  
Primary Examiner  
November 4, 2004